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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.														
10/685,237	10/14/2003	Kenneth B. Stokes	P-3586.01 Continuation 3	4635														
7590 Kenneth J. Collier Medtronic, Inc. 710 Medtronic Parkway N.E. Minneapolis, MN 55432		01/30/2008	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">KAHELIN, MICHAEL WILLIAM</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>3762</td><td></td></tr><tr><td colspan="2"><table border="1"><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>01/30/2008</td><td>PAPER</td></tr></table></td></tr></table>		EXAMINER		KAHELIN, MICHAEL WILLIAM		ART UNIT	PAPER NUMBER	3762		<table border="1"><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>01/30/2008</td><td>PAPER</td></tr></table>		MAIL DATE	DELIVERY MODE	01/30/2008	PAPER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/685,237

Applicant(s)

STOKES ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. Currently amended claim 36 recites an implantable delivery means with the functional limitation that it be for delivery/capable of delivering genetic material or protein. Examiner telephoned Applicant on 1/22/2008 to verify whether the genetic material or protein element was intended to be positively recited. Applicant affirmed that this element was intended to be positively recited and would be amended accordingly in the next correspondence, thus reciting something similar to: "An implantable system comprising: a genetic material or protein; and an implantable delivery means for delivering..." In the following Detailed Action, the Examiner has considered the genetic material or protein to be positively recited, but should be amended accordingly.

### ***Claim Objections***

2. Claims 39 and 43 objected to because of the following informalities: the claims are depended on cancelled claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 36-38 and 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by King (US 5,103,821, hereinafter "King").
5. In regards to claims 36-38, King discloses implanting functioning S-A nodal cells into the heart with a catheter ("Abstract" and col. 9, line 61-col. 10, line 8). Although King discloses implanting entire cells, these are functioning nodal cells that necessarily comprise functioning ion channels to support an action potential. For evidence that nodal cells necessarily contain functioning nodal cells, please see the attached Dokos reference. Further, because these are living, functional cells, the ion channels are formed of ion channel proteins, coded by RNA, which is coded by DNA.
6. In regards to claim 40, a bolus of cells is delivered (co. 9, line 61).
7. In regards to claims 41-43, since entire cells are delivered, and the claimed components are necessary features of functioning S-A node cells, King includes the claimed features.
8. In regards to claims 44 and 45, the implanted cells generate a depolarization wave, thus improve the ability to sense said (depolarization wave) cardiac signal (col. 9, line 62).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 39 and 46 are rejected under 35 U.S.C. 103(a) as obvious over King. King discloses the essential features of the claimed invention, including providing a catheter with a helical element (col. 10, line 4), and an implantable pacing electrode in conjunction with the cell therapy (col. 12, line 54), but does not expressly disclose a hollow helical element, or that the electrode detects signals resulting from the delivered material. It is well known in the pacing arts to provide hollow helical elements to provide the predictable results of concurrent fixation and injection, and to detect signals resulting from a delivered material, such as a pharmacological agent, to provide the predictable results of back-up pacing in case the delivered material is not entirely effective. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify King's invention by providing a hollow helical element to provide the predictable results of concurrent fixation and injection, and to

detect signals resulting from a delivered material to provide the predictable results of back-up pacing in case the delivered material is not entirely effective.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 36-46 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

*MWK*  
1/24/08

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**GEORGE R. EVANISKO**  
**PRIMARY EXAMINER**

*1/25/08*